

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

INGENUS PHARMACEUTICALS, LLC,

Plaintiff,

v.

HETERO USA, INC., HETERO LABS LTD., and
HETERO LABS LTD. UNIT-VI,

Defendants.

C.A. No. 1:24-cv-01025-JLH

**DEFENDANTS HETERO USA, INC., HETERO LABS LTD., AND
HETERO LABS LTD. UNIT-VI'S REPLY IN SUPPORT OF THEIR MOTION FOR
SUMMARY JUDGMENT**

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Despite Ingenus’s insistence that it is not making the argument that the “Nexus Court’s indefiniteness finding is incorrect,” D.I. 73 at 1 n.1, almost the entirety of Ingenus’s brief is dedicated to doing exactly that. Throughout, Ingenus repeatedly argues that Judge Rowland misunderstood the facts and came to the wrong conclusion in the *Nexus* case. While Ingenus is free to present those arguments to the Federal Circuit on appeal, “[u]nder *Blonder–Tongue*, a district court’s inquiry into whether the plaintiff was afforded a full and fair opportunity to litigate is quite narrow and does not involve a judgment on the merits.” *Pharmacia & Upjohn Co. v. Mylan Pharms., Inc.*, 170 F.3d 1373, 1380 (Fed. Cir. 1999).

Instead, “the court is only to decide whether the patentee had a full and fair opportunity to litigate the validity of his patent in the prior unsuccessful suit.” *Id.* (quoting *Stevenson v. Sears, Roebuck & Co.*, 713 F.2d 705, 709 (Fed. Cir. 1983)). On that point, Ingenus’s brief is virtually silent. Ingenus does not dispute that it was represented by counsel, who fully briefed the issue of indefiniteness before that court. Nor does Ingenus dispute that it had the opportunity to make any arguments and introduce whatever evidence it thought would be relevant to Judge Rowland’s summary judgment decision. Thus, the undisputed facts establish that Ingenus had a full and fair opportunity to litigate indefiniteness. *See Arunachalam v. Presidio Bank*, 801 F. App’x 750, 754 (Fed. Cir. 2020) (Appellant “was represented by counsel in the motions for summary judgment in *JPMorgan*. We find this proceeding to be a full and fair opportunity to litigate the issues.”).

Finally, Ingenus’s suggestion that Third Circuit law compels a different result is meritless. As Judge Bryson, sitting by designation in this district, recently explained, “with regard to the particular principles of collateral estoppel law that apply here, Federal Circuit law and Third Circuit law are the same.” *Ioengine, LLC v. PayPal Holdings, Inc.*, 607 F. Supp. 3d

464, 488 (2022) (D. Del. 2022) (Bryson, J., sitting by designation). “The choice of law question therefore does not matter to the disposition of this issue.” *Id.* Thus, Collateral estoppel applies and this Court should grant summary judgment.

ARGUMENT

I. The Final Judgment in the *Nexus* Case Is Sufficiently Firm to Have Preclusive Effect Under Both Federal Circuit and Third Circuit Law.

Ingenus does not dispute that under the binding Federal Circuit cases and the cases from this district cited in Hetero’s opening brief, the *Nexus* judgment is sufficiently final for collateral estoppel to apply. Instead, Ingenus argues that Third Circuit law compels a different result. This argument is meritless. Not only are the relevant legal principles dictated by the Supreme Court’s decision in *Blonder–Tongue*, there are no relevant distinctions between Federal Circuit law and Third Circuit law that would affect the determination of whether collateral estoppel applies here. Indeed, Judge Noreika applied Third Circuit law in *PureWick Corp. v. Sage Prods.* and held that finality “of course, can be satisfied by entry of final judgment on the issue” and that “the law is well settled that the pendency of an appeal has no effect on the finality or binding effect of a trial court’s holding.” No. 22-cv-102, 2023 WL 2734779, at *6 (D. Del. Mar. 31, 2023).

Moreover, as Federal Circuit Judge Bryson explained, Federal Circuit law—not Third Circuit law— would arguably apply if there were any material difference, but the issue can be avoided entirely because “with regard to the particular principles of collateral estoppel law that apply here, Federal Circuit law and Third Circuit law are the same.” *Ioengine*, 607 F. Supp. 3d at 488 (Bryson, J., sitting by designation). The “choice of law question therefore does not matter to the disposition of this issue.” *Id.*

Quoting the Third Circuit’s decision in *Dyndul v. Dyndul*, Ingenus asserts “[f]inality’ for purposes of issue preclusion is a more ‘pliant’ concept than it would be in other contexts.” D.I.

73 at 7 (quoting *Dyndul v. Dyndul*, 620 F.2d 409, 412 (3d Cir. 1980)). A cursory review of this case, and the other cases cited by Ingenus reveals, however, that the Third Circuit law on finality is the exact opposite of what Ingenus suggests in its brief. In the *Dyndul* case, the issue was whether to treat an interim order in a divorce case as “final” for purposes of collateral estoppel. The Third Circuit held that the interim order should be treated as final, reasoning that “[a]lthough the divorce proceeding as a whole has not yet been brought to an end, that portion of the order granting a divorce is more than sufficiently firm.” *Dyndul*, 620 F.2d at 412.

Likewise, the *Free Speech Coalition* case Ingenus relies on states that “[f]inality for purposes of issue preclusion is a more ‘pliant’ concept than it would be in other contexts,” and that finality “***may mean little more than that the litigation of a particular issue has reached such a stage that a court sees no really good reason for permitting it to be litigated again.***”¹ *Free Speech Coal., Inc. v. Att’y Gen. of U.S.*, 677 F.3d 519, 541 (3d Cir. 2012).

As another district court has explained, “in *Free Speech Coalition*, collateral estoppel did not apply because, in part, the ruling was one granting partial summary judgment, and because a final judgment had never been entered in the case, the order granting partial summary judgment was never appealable.” *Kline v. Hall*, No. 1:12-cv-1727, 2013 WL 1775061, at *4 (M.D. Pa. Apr. 25, 2013) (internal quotation marks omitted). The same is true of the *SoundView* case, which concerned whether to treat as final a partial summary judgment decision and a PTAB decision that had invalidated a subset of claims for a subset of the asserted patents. *See Sound View Innovations, LLC v. Walmart Inc.*, No. 19-cv-660, 2019 WL 7067056, at *2 (D. Del. Dec. 23, 2019), *report and recommendation adopted*, No. 19-cv-660, 2020 WL 136864 (D. Del. Jan.

¹ Any emphasis in this brief has been added.

13, 2020). Here, by contrast, the *Nexus* court found that the sole asserted patent was invalid and entered final judgment.

Ingenus’s remaining arguments are also without merit. First, Ingenus argues that the “procedural posture here—summary judgment with no technology presentation by expert witnesses, no hearing, and no opportunity for reargument—weighs against the conclusion that the parties were fully heard on the question of indefiniteness.” D.I. 73 at 8. Second, Ingenus argues that Judge Rowland’s “opinion expressed confusion about specific arguments and the testimony of Ingenus’s expert witness,” which “weigh[s] against the conclusion that the parties were fully heard as well as the conclusion that the Court issued a reasoned opinion.” D.I. 73 at 8. These arguments are just a rehash of Ingenus’s argument that it was denied a full and fair opportunity to be heard on indefiniteness, which Hetero addresses in full below. None of the factors Ingenus cites, however, suggest that the *Nexus* decision is in any way not “final.” Nor does Ingenus suggest that the Third Circuit law offers any support for its arguments.

Ingenus next argues that collateral estoppel should apply because it has appealed the *Nexus* decision.² As Hetero explained in its opening brief, “it is well settled that the pendency of an appeal has no effect on the finality or binding effect of a trial court’s holding.” *Upjohn*, 170 F.3d at 1381 (Fed. Cir. 1999) (citations omitted); *Galderma Labs Inc. v. Amneal Pharms., LLC*, 921 F. Supp. 2d 278, 281 (D. Del. 2012) (same); *Biogen Int’l GmbH v. Amneal Pharms. LLC*, 487 F. Supp. 3d 254, 267 (D. Del. 2020), *judgment entered*, No. 17-cv-823, 2020 WL 6277393

² Ingenus cites statistics suggesting that something less than 40 percent of indefiniteness decisions are reversed on appeal. D.I. 73 at 9 (citing Janet M. Smith, *Indefiniteness as an Invalidity Defense*, 58 Wm. & Mary L. Rev. 1403, 1408 (2017)) (“reversals premised on indefiniteness of the sort that was dispositive in *Teva V* averages almost 40 percent”). Another way of saying that is that over 60 percent of indefiniteness findings are affirmed on appeal and that Ingenus’s appeal is unlikely to be successful.

(D. Del. Sept. 22, 2020), *appeal dismissed*, No. 2021-1078, 2022 WL 16548075 (Fed. Cir. Oct. 31, 2022) (The “judgment is no less preclusive because it was rendered by a district court rather than the Federal Circuit and the judgment’s preclusive effect is in no way diminished because it is presently on appeal or because this case – where preclusion is sought – has already proceeded through trial.”); *DietGoal Innovations LLC v. Chipotle Mexican Grill, Inc.*, 70 F. Supp. 3d 808, 812 (E.D. Tex. 2014) (Bryson, J. sitting by designation) (“the collateral estoppel effect of a prior district court decision is not affected by the fact that an appeal has been taken from the decision.”); *Huron Holding Corporation v. Lincoln Mine Operating Co.*, 312 U.S. 183, 189 (1941) (“[I]n the federal courts the general rule has long been recognized that while appeal with proper supersedeas stays execution of the judgment, it does not—until and unless reversed—detract from its decisiveness and finality.”).

Ingenus, however, asserts that the Third Circuit “specifically allows courts to consider appeals when evaluating collateral estoppel.” D.I. 73 at 9. In support, it cites again to *Free Speech Coalition*, which states that the court can consider “whether that decision could have been, or actually was, appealed.” *Free Speech Coal., Inc.*, 677 F.3d at 541. In that case, the court declined to apply collateral estoppel to an “order granting partial summary judgment [that] was *never appealable*.” *Id.* Thus, while Ingenus is correct that the Third Circuit allows courts to consider appeals, the relevant fact is whether Ingenus *could* appeal. *Kline*, 2013 WL 1775061, at *4 n.9 (“Defendant Hall is therefore incorrect in asserting that Plaintiff’s failure to appeal is enough. The relevant fact is that Plaintiff could not appeal.”). Ingenus could and did appeal the *Nexus* judgment, so no exception to collateral estoppel applies here.

Ingenus also argues that collateral estoppel should not apply because it will impact “Ingenus’s ability to collect damages for infringement for the period of time after dismissal of

this case in the event Hetero launches its ANDA product prior to any Federal Circuit reversal of the *Nexus* Court’s ruling.” D.I. 73 at 9. This is a Hatch-Waxman case where Hetero does not have FDA approval to launch its product. Thus, there are no damages and Ingenus’s suggestion that there would be a launch while the appeal is pending is speculative. Nor is Ingenus without recourse, as Ingenus could seek injunctive relief from the Federal Circuit in such an event. *See, e.g., Novartis Pharmaceuticals Corporation v. MSN Pharmaceuticals, Inc.*, Case No. 25-1927, D.I. 13 (Fed. Cir., July 15, 2025) (order temporarily enjoining commercial marketing and sale generic version of Entresto® upon motion by appellant). Ingenus’s argument is also wrong as a matter of law because a “patentee may recover compensatory damages for infringing conduct done during the period that the claims were adjudged invalid or unenforceable.” *Matthews Annotated Patent Digest* § 30:139 (July 2025) (collecting cases). Moreover, the “Third Circuit has . . . cast doubt on the notion that generalized concepts of justice and equity constitute an independent ground for denying an estoppel defense.” *Biogen*, 487 F. Supp. 3d at 266.

Finally, Ingenus argues that “there was no opportunity for Ingenus to request review of the judgment in the *Nexus* Action” because “the court issued its opinion, entered final judgment, and closed the case on the same day.” D.I. 73 at 10. This argument is completely without merit as Ingenus has in fact sought review of the *Nexus* judgment by appeal to the Federal Circuit. It is also factually wrong as Rule 59 allows a party to file a motion to alter or amend a judgment within 28 days of the judgment. Fed. R. Civ. P. 59. Ingenus, however, filed no such motion.

In support of its argument, Ingenus cites to footnote 3 of *Nat’l R.R. Passenger Corp. v. Pennsylvania Pub. Util. Comm’n*, which quotes but does not analyze or apply the equitable factors for collateral estoppel listed in the Second Restatement of Judgments. 288 F.3d 519, 525 n.3 (3d Cir. 2002) (quoting Restatement (Second) of Judgments § 28). The Restatement makes

clear that the “inability to obtain review” factor that Ingenus relies on is concerned with the ability to obtain review *on appeal*, not reconsideration in the trial court. *See* Restatement (Second) of Judgments § 28 (1982) (providing an exception to collateral estoppel where “the party who lost on that issue is, for some other reason, disabled as a matter of law from obtaining review by appeal or, where appeal does not lie”).

II. Ingenus Had a Full and Fair Opportunity to be Heard on the Issue of Indefiniteness.

Ingenus argues that it “did not have a full and fair opportunity to litigate the issue of indefiniteness, [1] because the *Nexus* Court misinterpreted the mere mention of Refrigerated Conditions to be an affirmative test for stability,” and [2] because “the court did not understand which of the impurities mentioned in the ’952 Patent were relevant to the invention.” D.I. 73 at 11. Contrary to the Federal Circuit’s explicit instructions, these merit arguments are improperly focused on “whether the prior invalidity determination was correct,” which this Court is not permitted to evaluate in this posture. *See Stevenson*, 713 F.2d at 709. Moreover, these arguments are based on a misrepresentation of Judge Rowland’s summary judgment opinion.

“The Supreme Court made clear in *Blonder–Tongue* that the exception to the application of collateral estoppel based on a lack of understanding of the technology by a district court is a narrow one that will rarely be encountered.” *DietGoal Innovations LLC*, 70 F. Supp. 3d at 815. “The Federal Circuit has emphasized just how narrow that category is.” *Id.* “In particular, it does not extend to cases in which the essence of the patentee’s objection is simply that the court’s analysis of the patent and the issues of invalidity or infringement were erroneous.” *Id.*

Indeed, the cases Ingenus cites to all found that the prior courts had sufficient grasp of the technical subject matter and therefore the exception did not apply. The *CollegeSource* case, for example, emphasized that the “exception does not apply if the prior court reached a wrong result,

misread a couple of documents, or misconstrued a patent’s application.” *CollegeSource, Inc. v. AcademyOne, Inc.*, No. 08-cv-1987, 2015 WL 5638104, at *15 (S.D. Cal. Sept. 24, 2015), *aff’d*, 709 F. App’x 440 (9th Cir. 2017). And the *Kaiser Industries* case, which Ingenus quotes at length in its opposition brief, explained that not only have “cases interpreting the *Blonder-Tongue* doctrine . . . required a most stringent standard for demonstrating failure of scientific comprehension,” but also that “[n]o case has come to our attention holding that estoppel was inappropriate because of a failure of comprehension in the first trial.” *Kaiser Indus. Corp. v. Jones & Laughlin Steel Corp.*, 515 F.2d 964, 985 & n.93 (3d Cir.), *amend.*, 524 F.2d 1154.

Moreover, even if this Court were inclined to second-guess Judge Rowland’s summary judgment determination, Ingenus has failed to provide Hetero or the Court with the briefing and record necessary to undertake that analysis, much of which is under seal in the *Nexus* case. *See Kaiser Indus.*, 515 F.2d at 983 (In determining whether the *McLouth* courts “wholly failed to grasp” the scientific nature of the patented process, the Third Circuit “painstakingly read the *McLouth* opinions and briefs, in concert with the claims and specification of the Suess patent.”). Yet, it is apparent just by reviewing the summary judgment opinion itself that Ingenus has misrepresented Judge Rowland’s understanding and analysis of the technical issues in the case.

Ingenus first argues that Judge Rowland “failed to grasp the disclosure and interpreted the statement about Refrigerated Conditions to describe an affirmative test for stability required by the claims.” D.I. 73 at 12. This misrepresents Judge Rowland’s opinion, which considered the argument Ingenus raises here and explained that the question “is not whether ‘stable’ has a singular definition; the question is whether the patent provides a POSA notice of what is claimed by the word ‘stable’ such that a POSA can know when they risk infringement.” *Ingenus Pharmaceuticals v. Nexus Pharmaceuticals*, No. 1:22-cv-02868 (N.D. Ill.) (D.I. 215) at 8. Thus,

Judge Rowland did not “fail to grasp” anything, nor did she find that the patent required refrigerated stability; rather she found that the scope of the claims was indefinite.

Moreover, it was Ingenus’s *own expert*, Dr. Rabinow, who testified that the refrigerated stability conditions were potentially within the scope of the claims. *Id.* “In his opening report, Dr. Rabinow appeared to believe that, to infringe on the patent, an accused product must be stable under the Accelerated Conditions Test *and under Refrigerated Conditions.*” *Id.* at 8. While he later attempted to “disavow[] his earlier approach,” at “his deposition, Dr. Rabinow changed his opinion again, arguing that the patent did claim stability under Refrigerated Conditions.” *Id.* at 9. Thus, Ingenus was not denied a full and fair opportunity to litigate this issue, it just litigated the issue poorly.

Next, Ingenus argues that Judge Rowland “wholly failed to grasp the technical subject matter related to refrigeration” because she “did not understand that the inventors did not disclose research into specific aspects of stability under refrigeration, did not disclose experiments with potential compounds under refrigeration, did not disclose a test for evaluating potential compounds under such conditions, and did not claim to have invented compounds that would be tested or evaluated in such a manner.” D.I. 73 at 13-14.

This again grossly misrepresents Judge Rowland’s opinion. Judge Rowland not only understood that the specification did not disclose research into specific aspects of stability under refrigeration, that was a key part of her reasoning that the claims were indefinite:

To the extent that Dr. Rabinow is correct that, contrary to the position of Ingenus’s counsel, each claim must also be tested under Refrigerated Conditions, Ingenus has another problem. Other than the temperature, the patent provides no information about what parameters that test would involve — not the length of time the test should last, the acceptable impurities thresholds, or which impurities to test.

Ingenus Pharmaceuticals, LLC., No. 1:22-cv-02868 at 10.

Finally, Ingenus asserts that Judge Rowland “failed to grasp exactly which formulations were tested and which specific ones were ultimately claimed in the ’952 Patent” because she “failed to grasp that neither example 4 nor 5 [in Table 1 of the ’952 Patent] contains propylene glycol, and so neither formulation is claimed.” D.I. 73 at 14-15. But nowhere in her opinion does Judge Rowland state that Examples 4 and 5 are claimed formulations. Rather, in a footnote that does not factor significantly into the reasoning of the opinion, Judge Rowland notes that “it is not clear to the Court whether only impurities A, B, and D must be within acceptable limits or whether all the impurities contemplated in the patent’s Table 1 must be below acceptable limits,” and that is also unclear “what those acceptable limits are, as Table 1 shows impurity G at over 1% after one week in two examples.” *Ingenus Pharmaceuticals*, No. 1:22-cv-02868 at 7 n.3.

It is Ingenus who fails to grasp the import of Judge Rowland’s statements in footnote 3. The statements in footnote 3 are unobjectionably correct and relevant to the indefiniteness of the term “stable.” The ’952 Patent claims “stable” formulations. The inventors described Table 1 as describing “[c]yclophosphamide formulations prepared according to the Invention” and that the “stability data of the invention formulation is summarized in table 1.” D.I. 1-1 ’952 Patent at 4:15–19. The inventors tested both the claimed and unclaimed formulations for all impurities, including impurities E and G. *Id.*, Table 1. The fact that impurities E and G were detected in the unclaimed formulations but not in the claimed formulations suggests that those impurities are relevant to assessing stability, but the patent provides no further guidance on whether or how to test for those impurities. *Id.* This Court, however, need not address these merits issues at all.

CONCLUSION

For the foregoing reasons, and the reasons stated in Hetero’s opening brief, summary judgment should be granted in favor of Hetero on all claims.

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